

# TLC Trial Form ADE.04 Adverse Drug Experience Case Report Form

Center ID: \_\_\_\_\_ - \_\_\_\_\_  
Study ID: T \_\_\_\_\_ - \_\_\_\_\_

Send to:  
TLC Data Coordinating Center

**INSTRUCTIONS:** This form is to be filled out when there has been a serious **and** unexpected adverse drug experience. For the purposes of the TLC Trial, any event which results in inpatient hospitalization or death during the treatment phase is considered a serious and unexpected adverse drug experience, even if thought to be unrelated to study drug. The TLC Form ADECHK, documenting reporting procedures, should also be filled out. If this ADE was immediately life-threatening or resulted in death, the TLC physician must notify the FDA by phone within three working days.

## BACKGROUND INFORMATION

1. **Gender** ( )<sub>0</sub> Boy ( )<sub>1</sub> Girl  
2. **Date of Birth** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy

## ADVERSE EXPERIENCE

3. **Case report status** ( )<sub>1</sub> New case ( )<sub>2</sub> Follow-up report  
4. **Date of onset** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy  
5. **Inpatient hospitalization** ( )<sub>0</sub> No ( )<sub>1</sub> Yes  
a. **Date admitted** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy  
b. **Date discharged** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy ( )<sub>1</sub> Still in hospital as of this report  
c. **Hospital**  
\_\_\_\_\_  
*Name of hospital*  
\_\_\_\_\_  
*Address*  
\_\_\_\_\_  
*City State and Zip*  
6. **Date resolved** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy ( )<sub>1</sub> Unresolved as of this report  
7. **Life threatening** ( )<sub>0</sub> No ( )<sub>1</sub> Yes  
8. **Fatal** ( )<sub>0</sub> No ( )<sub>1</sub> Yes  
a. **Date of death** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy

*If this ADE was life-threatening or fatal, the TLC physician must notify the FDA by phone within the next three working days.*

9. Describe the events surrounding this ADE. Record all pertinent details, including concomitant medications, intercurrent events, and duration if less than 24 hours.

